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EXAMINER
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ART UNIT	PAPER NUMBER
1743	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,929	KHAN, TAHIR S.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Objections

1. Claim 11 is objected to because of the following informalities:

a) Claim 11: carbon is not a metal. Doped indium oxide is also not, strictly speaking, a metal; and

b) there are two claims labeled "20", so the claims have been renumbered, resulting in second Claim 20 – Claim 25 now being Claims 21-26. New Claims 22 and 23 now depend form Claim 21. New Claims 25 and 26 now depend from Claim 24.

2. Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ingress channels of Claim 6 must be shown or the features canceled from the claim. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 17 recites the limitation "said metallic electrodes" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim.

5. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 2, 4, 16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1).

Addressing Claim 1, Schibli teaches an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones.

See the abstract and Figure 1.

Although Schibli does not explicitly mention (in the abstract) having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Schibli teaches using the sensor to test levels of several different biochemicals, such as, sugar, urea, lactate, cholesterol, vitamin, troponin, and myoglobin, and Schibli implicitly discloses more than one reagent where he provides for "at least one" reagent.

Addressing Claim 2, at least two reaction zones are shown in Figure 1.

Addressing Claim 4, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use different reagent composition in order to test for different analytes.

Addressing Claim 16, Schibli does not mention having the test strip in a meter; however, one with ordinary skill in the art that the test strip shown in Figure 1 needs to be coupled to a meter in order to function; that is make measurements on a sample.

Addressing Claim 24, Schibli teaches a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and a reagent composition present in at least one of the reaction zones.

See the abstract and Figure 1.

Although Schibli does not explicitly mention (in the abstract) having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Schibli teaches using the sensor to test levels of several different biochemicals, such as, sugar, urea, lactate, cholesterol, vitamin, troponin, and myoglobin, and Schibli implicitly discloses more than one reagent where he provides for "at least one" reagent.

Schibli does not mention having the test strip in a meter; however, one with ordinary skill in the art that the test strip shown in Figure 1 needs to be coupled to a meter in order to function; that is take measurements on a sample.

9. Claims 1, 2, 4-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1).

Addressing Claim 1, Hodges et al. teach an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones.

See the abstract; Figures 5-11; and col. 5, ll. 33-37.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

Addressing Claim 2, at least two reaction zones are shown in Figures 5-11.

Addressing Claim 4, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use different reagent composition in order to test for different analytes.

Addressing Claim 5, an embodiment in which each reaction zone has its own ingress channel is disclosed in Figure 9 and 10 and in col. 7, ln. 63 – col. 8, ln. 2.

Addressing Claim 6, Figures 7 and 8 show an embodiment wherein at least two reaction zones have fluid ingress channels that merger to produce a single ingress channel to provide for fluid communication between the reaction zones and the external environment of the test strip.

Addressing Claims 7-10, 18, and 19, glucose oxidase dehydrogenase and ferricyanide are taught in col. 8, ll. 32-38.

Addressing claims 11, 12, 14, and 15, almost all of the possible electrode compositions claimed are disclosed in col. 9, ln. 62 – col. 10, ln. 10. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, because these metals have very good electrical conductivity and good corrosion resistance.

Addressing Claim 13, an effective cell volume of 1.5 μl is taught in col. 3, ll. 62-63.

Addressing Claims 16 and 20, a meter is implied by col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time.

Addressing Claim 17, Hodges et al. teach a means for determining the concentration of analyte in a physiological sample the means comprising

an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference metallic electrodes separated by a spacer layer and at least one reagent in a reaction zone.

See the abstract; Figures 5-11; and col. 5, ll. 33-37; and col. 9, ln. 62 – col. 10, ln. 10.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

As for the claimed steps of applying a physiologic sample, detecting an electrical signal, and relating the electrical signal to amount of analyte in the sample, these may be found in col. 2, ll. 40-65.

Addressing Claim 24, Hodges et al. teach a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and a reagent composition present in at least one of the reaction zones; and

(b) a meter (implied by col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time).

See the abstract; Figures 5-11; and col. 5, ll. 33-37.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

10. Claims 1, 2, 4, 7-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1).

Addressing Claim 1, Bergkuist et al. teach an electrochemical test strip comprising

a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have

a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Addressing Claim 2, at least two reaction zones are shown in Figures 2 and 3.

Addressing Claim 4, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use different reagent composition in order to test for different analytes.

Addressing Claims 7-10, 18, and 19, although Bergkuist et al. disclose measuring glucose (col. 8, ll. 34-39), no particular redox reagent system is disclosed. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a redox reagent system comprising glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Bergkuist et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 38-45.

Addressing Claims 11, 12, 14, and 15, the electrode composition in Bergkuist et al. are not known; however, Applcant's claimed possible electrode compositions were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Bergkuist et al. because these metals have very good electrical conductivity and good corrosion resistance.

Addressing Claim 13, the volume of the reaction zones in Bergkuist et al. so they will be assumed to be outside Applicant's claimed range; however, barring evidence to eth contrary, such as unexpected results, having reaction zones within Applicant's claimed range is just a matter of scaling down the test strip. As seen in Hodges et al. col. 3, ll. 60-63 it was known at the time of the invention to have opposing electrodes closely spaced to form a cell having an effective volume of 1.5 μl.

Addressing Claims 16 and 20, a meter is implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for dispslaying the measurement results in human-readable form.

Addressing Claim 17, Bergkuist et al. teach a means for determining the concentration of analyte in a physiological sample the means comprising

an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and at least one reagent in a reaction zone.

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

The electrode composition in Bergkuist et al. are not known; however, metallic electrode compositions were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Bergkuist et al. because these metals have very good electrical conductivity and good corrosion resistance.

As for the claimed steps of applying a physiologic sample, detecting an electrical signal, and relating the electrical signal to amount of analyte in the sample, it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform these steps because the purpose of the test strip is measuring the levels of substance in body fluid, such as blood. See col. 1, ll. 1-24.

Addressing Claim 24, Bergkuist et al. teach a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a meter (implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for displaying the measurement results in human-readable form).

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would

have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) as applied to Claims 1, 2, 4, 16, and 24 above, and further in view of Yee (US 5,672,256). Schibli appears to only disclose a different reagent composition in the reaction zones. Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Schibli because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4-20, and 24 above, and further in view of Yee (US 5,672,256). Hodges et al. appears to only disclose a different reagent composition in the reaction zones. Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Hodges et al.

because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4, 7-20, and 24 above, and further in view of Yee (US 5,672,256). Bergkuist et al. teach having arrays of identical sensors in col. 10, ll. 1-13. In any event, Yee teach having a plurality of electrochemical reaction zones each having the same reagent composition. See the abstract; Figures 3 and 4; and col. 4, ll. 22-28. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the same reagent composition in the reaction zones as taught by Yee in the invention of Bergkuist et al. as modified by Hodges et al. because then a more accurate measurement can be obtained by averaging the measurements in the different reaction zones. See in Yee col. 2, ll. 44-57.

14. Claims 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) as applied to Claims 1, 2, 4, 16, and 24 above, and further in view of Hodges et al. (US 6,413,410 B1).

Addressing Claims 7-10, Enzyme reagent is disclosed in the Schibli abstract; however, nothing more is known about the redox reagent system. It would have been obvious to one with

ordinary skill in the art at the time the invention was made to use at least a redox reagent system comprising glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Schibli et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 38-45 in Hodges et al..

Addressing Claims 11, 12, 14, and 15, the electrode composition in Schibli is not known; however, Applcant's claimed possible electrode compositions were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Schibli because these metals have very good electrical conductivity and good corrosion resistance.

Addressing Claim 13, the volume of the reaction zones in Schibli so they will be assume d to be outside Applicant's claimed range; however, barring evidence to eth contrary, such as unexpected results, having reaction zones within Applicant's claimed range is just a matter of scaling down the test strip. As seen in Hodges et al. col. 3, ll. 60-63 it was known at eh time of the invention to have opposing electrodes closely spaced to form a cell having an effective volume of 1.5 μl.

15. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) in view of Hodges et al. (US 6,413,410 B1).

Addressing Claim 17, Schibli teaches a means for determining the concentration of analyte in a physiological sample the means comprising

an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and at least one reagent in a reaction zone.

See the abstract and Figure 1.

Schibli does not explicitly mention (in the abstract) having reagent in each of the reaction zones; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Schibli teaches using the sensor to test levels of several different biochemicals, such as, sugar, urea, lactate, cholesterol, vitamin, troponin, and myoglobin, and Schibli implicitly discloses more than one reagent where he provides for "at least one" reagent.

Schibli also does not mention the composition of the electrodes; however, Applicant's metal electrodes were known at the time of the invention, as shown, for example, by col. 9, ln. 62 – col. 10, ln. 9 in Hodges et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use gold or palladium, for example, as taught by Hodges et al. in the invention of Schibli because these metals have very good electrical conductivity and good corrosion resistance.

As for the claimed steps of applying a physiologic sample, detecting an electrical signal, and relating the electrical signal to amount of analyte in the sample, it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform these steps because the purpose of the test strip is measuring the levels of substance in body fluid, such as blood.

Addressing Claim 18 and 19, Measuring blood sugar and providing an enzyme reagent is disclosed in the Schibli abstract; however, nothing more is known about the redox reagent system. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use at least a redox reagent system comprising glucose oxidase and a mediator, such as ferricyanide, to measure glucose in the invention of Schibli et al. because this redox reagent system was commonly used at the time of the invention to measure glucose. See col. 1, ll. 38-45 in Hodges et al.

Addressing Claim 20, Schibli does not mention having the test strip in a meter; however, one with ordinary skill in the art that the test strip shown in Figure 1 needs to be coupled to a meter in order to function; that is take measurements on a sample.

16. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) in view of Leader et al. (US 5,421,981).

Addressing Claim 21, Schibli teaches an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones.

See the abstract and Figure 1.

Although Schibli does not explicitly mention (in the abstract) having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Schibli teaches using the sensor to test levels of several different biochemicals, such as, sugar, urea, lactate, cholesterol, vitamin, troponin, and myoglobin, and Schibli implicitly discloses more than one reagent where he provides for "at least one" reagent.

Schibli does not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Schibli because then the operator won't have to look for or store the appropriate

analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, Schibli does not mention having the test strip in a meter; however, one with ordinary skill in the art that the test strip shown in Figure 1 needs to be coupled to a meter in order to function; that is make measurements on a sample.

17. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) in view of Leader et al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Schibli as modified by Leader et al. do not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Schibli as modified by Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

18. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) in view of Leader et al. (US 5,421,981).

Addressing Claim 21, Hodges et al. teach an electrochemical test strip comprising

(a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and

(b) a reagent composition present in at least one of the reaction zones.

See the abstract; Figures 5-11; and col. 5, ll. 33-37.

Although Hodges et al. do not explicitly mention having reagent in each of the reaction zones, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Hodges et al. teach using the sensor to test levels of biochemicals other than glucose and of other chemicals. See col. 10, ll. 25-35.

Hodges et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, a meter is implied by Hodges et al. in col. 3, ll. 52-59, which discloses coupling the test strip to means for applying an electric potential to the electrodes and a means for measuring current change with time.

19. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) Leader al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Hodges et al. as modified by Leader et al. do not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Hodges et al. as modified by Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

20. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) and Leader et al. (US 5,421,981).

Addressing Claim 21, Bergkuist et al. teach an electrochemical test strip comprising

a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer.

See the abstract and Figures 2 and 3.

Although Bergkuist et al. do not explicitly mention having reagent in each of the reaction zones, having an ionophore in each reaction zone is disclosed. See col. 6, ll. 23-30. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have a reagent in each of the reaction zones because Bergkuist et al. disclose that the sensor may be employed to test for biochemicals such as glucose and lactate. See col. 8, ll. 34-41.

Bergkuist et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Bergkuist et al. as modified by Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the

physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

Addressing Claim 23, a meter is implied by Bergkuist et al. in col. 3, ll. 5-12, which teaches coupling the test strip to a means for displaying the measurement results in human-readable form.

21. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) and Leader et al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). Bergkuist et al. as modified by Hodges et al. and Leader et al. do not disclose a lance, although Leader et al. do disclose a syringe (col. 14, ll. 38-41).

Guruswamy et al. disclose that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by Guruswamy et al., instead of, or in addition to, a syringe in the invention of Bergkuist et al. as modified by Hodges et al. and Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

22. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schibli (EP 1167538 A1) as applied to Claims 1, 2, 4, 16, and 24 above, and further in view of Leader et al. (US 5,421,981).

Schibli does not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample or an analyte standard as taught by Leader et al. in the invention of Schibli because then the operator won't have to look for or store the appropriate analyte standard or means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

23. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4-20, and 24 above, and further in view of Leader et al. (US 5,421,981).

Hodges et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample or an analyte standard as taught by Leader et al. in the invention of Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

24. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergkuist et al. (US 6,123,820) in view of Hodges et al. (US 6,413,410 B1) as applied to Claims 1, 2, 4, 7-20, and 24 above, and further in view of Leader et al. (US 5,421,981).

Bergkuist et al. do not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample or an analyte standard as taught by Leader et al. in the invention of Bergkuist et al. as modified by Hodges et al. because then the operator won't have to look for or store the appropriate analyte standard and means for obtaining the

physiological sample. By having these items together in a kit, it is more convenient for whoever is going to use the test strip.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7719 for regular communications and (703) 305-5433 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
September 9, 2002